IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

ARTHUR and ESTHER FULLER Plaintiffs	§	
VS	§	CIVIL ACTION NO. A11CA 093LY
XANODYNE PHARMACEUTICALS, INC. Defendants	§	

PLAINTIFF'S ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

Plaintiffs, ARTHUR and ESTHER FULLER file this, their Original Complaint against Defendants, XANODYNE PHARMACEUTICALS, INC., and or causes of action, would respectfully show:

A. PARTIES

1. Plaintiffs, ARTHUR and ESTHER FULLER are individuals who are citizens of the State of Texas and a resident of Bell County, Texas.

2. Defendant XANODYNE PHARMACEUTICALS, INC. is a corporation with a principal place of business in Florence, Kentucky, which conducts business in and throughout the State of Texas. XANODYNE is principally engaged in the manufacture and sale of pharmaceuticals. Service of process may be had upon Defendant by serving its Registered Agent for service, Xanodyne Pharmaceuticals, Inc., 7300 Turfway Road, Suite 300, Florence, KY 41042.

B. JURISDICTION AND VENUE

3. The Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the action is between the citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendant, XANODYNE

PHARMACEUTICALS, INC., is incorporated and has its principal place of business in a state other than the state in which the named Plaintiffs reside.

4. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Western District of Texas.

NATURE OF THE CASE

6. This action is brought on behalf of Plaintiffs, ESTHER FULLER, who was prescribed, purchased and correctly used Darvocet, also known generically as Propoxyphene Napsylate and Acetaminophen and ARTHUR FULLER, spouse of Plaintiff ESTHER FULLER.

7. Defendant, XANODYNE PHARMACEUTICALS, INC. (hereinafter referred to as "Defendant") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Darvocet for use as a prescription pain management medication.

8. Defendant concealed their knowledge of Darvocet's defects, from Plaintiff, the Food and Drug Administration (hereinafter referred to as "FDA"), the public in general and/or the medical community specifically.

9. When warning of safety and risks of Darvocet, Defendant negligently and/or fraudulently represented to the medical and healthcare community, the FDA, to Plaintiffs and the public in general, that Darvocet had been tested and was found to be safe and/or effective for its indicated use.

10. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiffs, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical

community in particular, to recommend, dispense and/or purchase Darvocet for use as a prescription pain management medication, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

11. Defendant negligently and improperly failed to perform sufficient tests, if any, concerning Darvocet's potential to cause cardiotoxicity and, more specifically, potentially fatal cardiac arrhythmias, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other prescription pain management medications, which does not entirely and/or necessarily apply to Darvocet.

12. As a result of the defective nature of Darvocet, those persons who use and/or used and relied on Darvocet have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, heart arrhythmias, mayocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

13. Plaintiff herein has sustained certain of the above health consequences due to her use of Darvocet.

14. Defendant concealed its knowledge of the defects in its product from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

15. Consequently, Plaintiff seeks compensatory damages as a result of her use of Darvocet, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be greatly increased risk of serious and dangerous side effects including heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and

personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

16. Prior to September 2009, Plaintiff, ESTHER FULLER, did not have a pre-existing cardiac history and had never suffered a cardiac arrhythmia.

17. Plaintiff, ESTHER FULLER, was prescribed Darvocet for pain management in or about August 2009.

18. As a result of using Defendant's drug Darvocet, Plaintiff ESTHER FULLER, was caused to suffer cardiovascular injuries and cardiac arrhythmias, including but not limited to atrial fibrillation since September 2009.

19. Plaintiff, ESTHER FULLER used Darvocet in the manner in which it was prescribed to her at or about the time she suffered cardiovascular injuries and arrhythmias, including but not limited to, atrial fibrillation.

20. In order to treat her arrhythmia and life threatening cardiac condition, Plaintiff, ESTHER FULLER, has undergone extensive treatment and been told that her condition may cause her untimely death.

21. Plaintiff, ESTHER FULLER, was caused to sustain severe, permanent and life threatening personal injuries, pain, suffering, emotional distress, lifelong fear of premature death and the need for continued lifelong cardiac monitoring, treatment and medications.

22. The injuries and damages sustained by Plaintiff, ESTHER FULLER, were caused by Defendant's drug, Darvocet.

PARTY DEFENDANT

23. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC. was at all relevant times a corporation organized under the laws of the State of Kentucky, with its principal place of business located in the State of Kentucky.

24. Upon information and belief, at all times relevant, Defendant XANODYNE PHARMACEUTICALS, INC. has transacted and conducted business in the State of Texas and derived substantial revenue from interstate commerce.

25. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., expected or should have expected that its acts would have consequences within the United States of America, and Bell County, Texas and within the confines of the Western District of Texas in particular and derived substantial revenue from interstate commerce.

26. Upon information and belief, at all times relevant, Defendant XANODYNE PHARMACEUTICALS, INC. was in business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Darvocet for use as a prescription management medication.

27. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC. is the holder of approved New Drug Application for Darvocet.

FACTUAL BACKGROUND

28. At all times relevant, Defendant was and remains in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendant who has designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Darvocet for use as a prescription pain management medication.

29. At all times relevant, Defendant focused its sales on pain management products including Darvocet because the area of pain management offers attractive commercial opportunities in significant markets in the United States, see http://www.xanodyme.com/strategy.asp (as of December 9, 2010).

30. At all times relevant, Defendant affirmatively decided not to take part in full discovery research of its products because Defendant believed that it was more beneficial for it to advance products quickly through abbreviated developmental pathways in order to decrease the time and cost of bringing a new drug to market, see http://www.xanodyme.com/strategy.asp (as of December 9, 2010).

31. By using a strategy of moving its products through the research and development process expeditiously Defendant believes it can reach its goal of becoming a leading integrated specialty pharmaceutical company that develops and commercializes new products for significant markets in pain management, http://www.xanodyme.com/strategy.asp (as of December 9, 2010).

32. In 2009, about ten million people in the U.S. received prescriptions for Darvocet-related drugs according to the FDA.

33. Upon information and belief, Adverse Event ("AE") data maintained by the FDA indicates staggering, serious AEs, including heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and or sudden death.

34. Defendant ignored the correlation between the use of Darvocet and the increased risk of developing potentially fatal heart arrhythmias, despite the wealth of scientific and medical evidence available.

35. In June 2009, the European Medicines Agency ("EMEA") recommended that marketing authorizations for Darvocet be withdrawn across the European Union for safety concerns.

36. Despite being petitioned by public interest groups to investigate whether Darvocet was linked to serious and potentially fatal heart arrhythmias, Defendant refused to do so until July 2009, when it was ordered by the FDA to conduct a safety study assessing unanswered questions about the effects of Darvocet on the heart.

37. Plaintiff, ESTHER FULLER, experienced a potentially fatal cardiac arrhythmia as a result of taking Darvocet in September 2009 and again in January 2010. In January 2010, Plaintiff was hospitalized, died but was able to be resuscitated. As of the date of the filing of this petition, Plaintiff is currently hospitalized.

38. The results of the study ordered by the FDA indicated that even when taken at recommended doses, Darvocet cause significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram ("ECG" or "EKG"), can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

39. On November 19, 2010, the FDA announced that Defendant XANODYNE PHARMACEUTICALS, INC., had agreed to halt all U. S. Marketing of Darvocet after it was determined that the drugs benefits were outweighed by the risks associated with its use, specifically the potential of the drug to cause serious and potentially fatal heart arrhythmias.

40. The use of Darvocet creates unique and dangerous risks compared to other prescription pain management medications. These risks include, heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death.

41. That Defendant did not provide adequate warnings to doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been reported by the medical community.

42. By reason of the foregoing, Plaintiff has developed dangerous side effects including, heart arrhythmias and other adverse cardiovascular events, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

43. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered serious and dangerous side effects including, heart arrhythmias and other adverse cardiovascular events, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named consequences.

44. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendant's drug Darvocet.

FEDERAL REQUIREMENTS

45. Defendant had an obligation to comply with the law in the manufacture, design and sale of Darvocet.

46. Upon information and belief, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

47. With respect to the prescription drug Darvocet, the Defendant, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug Darvocet is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage, or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug Darvocet is adulterated pursuant to 21 U.S.C. §351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Darvocet and such deviations are not plainly stated on their labels.

c. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. The prescription drug Darvocet is misbranded pursuant to 21 U. S. C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug Darvocet does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (e) route or method of administration or application.

h. The Defendant violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug Darvocet is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updates as new information became available that caused the labeling to become inaccurate, false or misleading.

j. The Defendant violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Darvocet cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendant violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Darvocet.

l. The Defendant violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Darvocet are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

m. The prescription drug Darvocet is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug Darvocet is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendant violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Darvocet and other drugs in the same pharmacologically active and chemically related class.

p. The Defendant violated 21 CFR § 201.57 because the possibility that a patient could develop cardiac arrhythmias, while significantly more severe than the other reactions listed in the adverse reactions section, was not listed by Defendant before the other less serious adverse reactions on the labeling of the prescriptions drug Darvocet.

q. The prescription drug Darvocet is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug Darvocet violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug Darvocet violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug Darvocet violates 21 CFR § 211.165 because the test methods employed by the Defendant are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug Darvocet violates 21 CFR § 211.165 in that the prescription drug Darvocet fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug Darvocet violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Darvocet were not followed.

w. The prescription drug Darvocet violates 21 CFR § 310.303 in that the prescription drug Darvocet is not safe and effective for its intended use.

x. The Defendant violated 21 CFR § 310.303 because the Defendant failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to report adverse events associated with the prescription drug Darvocet as soon as possible or at least within 15 days of the initial receipt by the Defendant of the adverse drugs experience.

z. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Darvocet, and evaluating the cause of the adverse event.

aa. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow up."

dd. The Defendant violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Darvocet or otherwise received by the Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendant violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing

15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendant violated 21 CFR § 314.80 by failing to submit a copy of published articles from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

47. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendant negligent per se.

FIRST CAUSE OF ACTION
MANUFACTURER'S DUTY AND PRODUCTS LIABILITY
TEX.CIV.PRAC.REM. CODE §82.002

48. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows:

49. At all times relevant to this action, Defendant was the manufacturers and/or supplier of Darvocet products and/or their pharmaceutical ingredients, placing the prescription drug into the stream of commerce.

50. Defendant had a duty to manufacture, design, formulate, produce, create, make, construct, and/or assemble a pain medication that would conform to the chemical composition, formula, or performance standards of Defendant and would not cause users to suffer unreasonable, dangerous side effects such as heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death.

51. Defendant breached this duty to manufacture, design, formulate, produce, create, make, construct, and/or assemble a pain medication that would conform to the chemical composition, formula, or performance standards of Defendant in that Defendant knew or should have known

its Darvocet products were defective and would cause its users to suffer severe side effects in consequence of using the Darvocet products. Defendant's Darvocet products did not function as intended and, or in the alternative, created a high risk of unreasonable, dangerous side effects; to wit: heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death.

52. The Darvocet products were expected to and did reach Plaintiff without substantial change in the condition in which they were manufactured and sold.

53. Defendant's Darvocet products and their pharmaceutical ingredients in varying dosages were defectively manufactured at the time that they left Defendant's control.

54. The Darvocet products and their pharmaceutical ingredients were unsafe for normal or reasonably anticipated use.

55. Defendant's Darvocet products were unreasonably dangerous in that they were unsafe when used for the intended purpose for medical treatments.

56. The Darvocet products were more dangerous than an ordinary consumer would expect, and the foreseeable risk or injuries from their administration exceeded their associated benefits.

57. Defendant wrongfully permitted defective pharmaceuticals to be placed into the stream of commerce, in the following ways:

a. Defendant failed to exercise reasonable care in the manufacture of their Darvocet products and/or their pharmaceutical ingredients;

b. Defendant failed to exercise reasonable care in the inspection of their Darvocet products and/or their pharmaceutical ingredients;

c. Defendant failed to exercise reasonable care in the packaging of their Darvocet products and/or their pharmaceutical ingredients;

d. Defendant failed to provide any or adequate warnings about the risks and dangers associated with the use of their Darvocet products, as alleged herein and/or their pharmaceutical ingredients;

e. Defendant failed to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of their Darvocet products and/or their pharmaceutical ingredients;

f. Defendant failed to recall, withdraw, and remove their Darvocet products and/or their pharmaceutical ingredients from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Defendant failed to promptly respond to data, reports, and publications describing problems associated with their Darvocet products and/or their pharmaceutical ingredients by conducting adequate analysis, testing, and surveillance;

h. Defendant failed to implement pre-marketing and post-marketing measures to notify and warn Plaintiff as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said Darvocet products and/or their pharmaceutical ingredients, and to recall the defective Darvocet products;

i. Defendant failed to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;

j. Defendant failed to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and import requirements for the Darvocet products and all component parts, including, but not limited to, the API.

58. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

59. Disregarding continuous findings of the extent of danger posed by Darvocet containing products, Defendant continued to manufacture design, formulate, produce, and create, make, construct, and/or assemble its Darvocet products to consumers, including Plaintiff.

60. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury, physically, psychologically, and economically as a result of Defendant's failure to exercise ordinary care.

61. Plaintiff believes Defendant failed to exercise reasonable care in its production of its Darvocet products. However, even if Defendant is found to have exercised reasonable care in the production of its Darvocet products, Defendant is still liable for the damages and injuries suffered by Plaintiffs pursuant to ORC § 2307.74.

62. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to, heart arrhythmias, other adverse cardiovascular events, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

SECOND CAUSE OF ACTION
INHERENTLY UNSAFE AND DESIGNED DEFECT PRODUCT
TEX.CIV.PRAC.REM. CODE §82.004 AND §82.005

63. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows:

64. At all times herein mentioned, Defendant manufactured, designed, formulated, produced, created, made, constructed, and/or assembled Darvocet products use by Plaintiff.

65. Defendant's Darvocet products were defective in that, at the time of release of these products into the stream of commerce by Defendant, the medical benefits of the products were far outweighed by the foreseeable risks associated with the formulation of the products.

66. Defendant's Darvocet products were in an unsafe, defective, and inherently dangerous condition when they were placed by Defendant into the stream of commerce. The dangerous condition of these products was unreasonably dangerous to its users, Plaintiff in particular.

67. Defendant's Darvocet products were in a defective condition and unsafe, and Defendant knew, had reason to know, or should have known that these products were defective and unsafe, even when used as prescribed by Defendant and prescribing physicians.

68. The nature and magnitude of the risk of harm associated with the design and formulation of Defendant's Darvocet products, including, but not limited to, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, is high in light of the intended and reasonably foreseeable uses of the products.

69. The formulation of Defendant's Darvocet products is more dangerous than a reasonably prudent consumer would expect when used in the intended or foreseeable manner. These products were more dangerous than Plaintiff expected.

70. The benefits of Defendant's Darvocet products do not outweigh the risks.

71. A practical and medically feasible alternative drug was available for Plaintiff that would have prevented the harm for which Plaintiff suffered and remedied the pain for which Plaintiff consumed Defendant's Darvocet product.

THIRD CAUSE OF ACTION
FAILURE TO WARN
TEX.CIV.PRAC.REM.CODE §82.007

72. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows:

73. Defendant had a duty to warn Plaintiff of the risks associated with consuming Defendant's Darvocet-containing products; namely, that these products may cause heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death. Defendant knew or should have known about these risks.

74. Defendant failed to provide adequate warnings or instruction that a drug manufacturer, exercising reasonable care, would have provided concerning these risks and other health concerns for which Plaintiff as suffered.

75. Defendant's Darvocet-containing products are defective due to inadequate post-marketing warning or instruction.

76. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling the Darvocet products which are defective due to inadequate warning or instruction.

FOURTH CAUSE OF ACTION
LOSS OF CONSORTIUM

77. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows:

78. As a direct and proximate result of Defendant's wrongful conduct detailed above, Plaintiff ESTHER FULLER, spouse of Plaintiff ARTHUR FULLER, was deprived of the care, consideration, compassion, consortium and concern of Plaintiff ESTHER FULLER, and has suffered injuries and damages thereby.

79. Plaintiff ARTHUR FULLER is thereby entitled to an award of damages for loss of consortium.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

a. For an award of compensatory damages, including damages against Defendant for past and future damages, medical and hospital expenses, loss of income, loss of consortium, pain and suffering, medical monitoring and other damages according to proof at trial, but believed to be in an amount greater than $75,000.00.

b. For an award of punitive or exemplary damages against Defendant for the wanton, willful, fraudulent, reckless acts of Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish and deter future similar conduct.

c. For reasonable attorneys' fees and costs;

d. For pre-judgment interest; and

e. For such further and other relief the court deems just, equitable, and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Respectfully submitted,

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By: _____
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